Appl. No. : **10/667,580**
Filed : **September 22, 2003**

REMARKS

By way of summary, Claims 1–11 were pending in this application with Claims 1 and 3–11 withdrawn. By this Amendment, Claim 2 has been amended and Claim 12 has been added. These amendments are made without prejudice, and Applicants respectfully reserve the right to pursue claims with the original or broader scope in a continuation. Applicant respectfully submits that amended Claim 2 and new Claim 12 are patentable, as explained herein.

Rejection under §102(b)

Claim 2 was rejected in the Office Action dated May 30, 2006, as being anticipated by U.S. Patent No. 6,626,858 to Lynch. Applicants respectfully submit that Lynch does not anticipate Claim 2 at least because it does not disclose, teach, or suggest all the limitations of amended Claim 2.

Lynch discloses several shunt devices for "decompressing elevated intraocular pressure in eyes affected by glaucoma by diverting excess aqueous humor from the anterior chamber of the eye into Schlemm's canal where post-operative patency can be maintained with an indwelling shunt device which surgically connects the canal with the anterior chamber." See Abstract. As shown in Figure 2, reproduced here, the Lynch device includes a plurality of openings 30 in an outflow portion 25 that allow fluid to pass therethrough when the outflow portion 25 is positioned in Schlemm's canal. As explained by Lynch, the outflow portion 25 is connected to a proximal portion 10 that extends through the trabecular meshwork when the shunt is implanted in the eye. The proximal portion 10 is connected to a proximal portion portal 18 that resides in the anterior chamber and allows fluid to flow into the shunt when implanted.

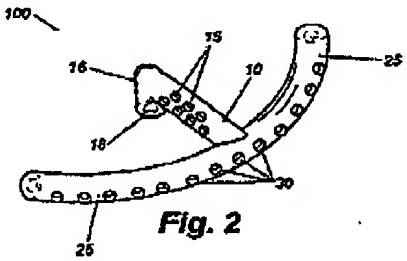

Fig. 2

Applicants respectfully submit that Claim 2 is not anticipated by Lynch because the reference does not disclose all the limitations of the claim. For example, Claim 2 recites, in part, that the outflow portion is shaped and sized to be "received at least partially within Schlemm's canal *regardless of a rotational orientation* of the outflow portion about said longitudinal implant axis during said introduction." Lynch discloses a curved distal portion 25 that is configured to have the same or similar annular shape as Schlemm's canal. If the outflow portion

25 were rotated about any segment of its (curvilinear) longitudinal axis, the ends of the outflow portion 25 would likewise rotate out of the annular shape of Schlemm's canal and the outflow portion 25 would not fit within Schlemm's canal. Additionally, the proximal portion 10 would also rotate as the outflow portion 25 rotates, and the proximal portion 10 would not reside within the anterior chamber. The Lynch device must be placed in the eye in a specific rotational orientation with respect to the axis of the outflow portion if it is to reside in Schlemm's canal. Accordingly, the device is not received within Schlemm's canal regardless of rotational orientation with respect to the longitudinal axis of the outflow portion 25, as recited in Claim 2.

Likewise, if the longitudinal axis were taken along the long axis of the proximal portion 10, rotation of the implant about this axis would also preclude the Lynch device from residing in Schlemm's canal. For example, if the proximal portion 10 were rotated ninety degrees about its axis from its intended orientation, the outflow portion 25 would also rotate to an orientation roughly perpendicular to Schlemm's canal. In this configuration, the proximal portion would extend into the anterior chamber, but the outflow portion 25 would be perpendicular to Schlemm's canal, thus preventing the outflow portion 25 from residing in Schlemm's canal. The Lynch stent does not disclose, teach, or suggest all the limitations of Claim 2 at least because the Lynch stent must be implanted into the eye in a specific rotational orientation with respect to both the longitudinal axis of the proximal portion 10 and with respect to the longitudinal axis of the outflow portion 25. Deviations from this specific rotational orientation will make the Lynch device unsuitable for the intended implantation and unable to conduct fluid from the anterior chamber to Schlemm's canal. In contrast, Claim 2 recites, in part, that the outflow portion is sized and shaped to be received "regardless of a rotational orientation of the outflow portion about said longitudinal implant axis during said introduction." Accordingly, Applicants respectfully submit that Claim 2 is not anticipated by Lynch and that the anticipation rejection of Claim 2 should be withdrawn.

New Claim 12

Independent Claim 12 has been added and recites steps for a method of treating glaucoma. Claim 12 recites a method for implanting an implant having a number of the features recited in Claim 2, and Applicants respectfully submit that Claim 12 is in condition for

allowance. For example, Claim 12 recites the step of delivering the implant from the anterior chamber into Schlemm's canal, i.e., delivering the implant *ab interno*. In contrast, Lynch teaches implantation of the implant through a conjunctival flap and through the sclera into Schlemm's canl, i.e., *ab externo*. Altering Lynch's method of delivery from ab externo to ab interno would be difficult, if not impossible. For example, using Lynch's implant of Figure 2 would require a long transverse incision through the trabecular meshwork and Schlemm's canal to fit the crossbar of the T-shaped implant into Schlemm's canal. Such a procedure would create bleeding within the eye and would increase the likelihood of ocular morbidity and visual impairment. Accordingly, Applicants respectfully submit that Lynch does not disclose, teach, or suggest the limitations recited in Claim 12, and Applicants respectfully request allowance of Claim 12 in addition to Claim 2.

CONCLUSION

In view of the foregoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly.

Applicants respectfully submit that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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